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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/183,824	10/30/98	RAJU T	P1097 DRC

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EXAMINER	
CUSTER, P	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 06/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/183,824	Applicant(s) Raju et al.
	Examiner Tara Custer	Group Art Unit 1644

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-44* is/are pending in the application.

Of the above, claim(s) *8, 9, 17-19, 21-34, and 40* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-7, 10-16, 20, 35-39, and 41-44* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20 and 35-44, drawn to a pharmaceutical composition comprising glycoprotein and an article of manufacture, classified in class 514, subclass 885.

II. Claims 21-30, drawn to a method of producing the glycoprotein composition, classified in class 435, subclass 68.1.

III. Claims 31-34, drawn to a method of treatment of a disease state, classified in class 424, subclass 133.1.

2. Inventions I and II are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the product as claimed may be made by other processes such as chemical deglycosylation by hydrazinolysis.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the products as claimed can be used in a materially different process such as other detection assays.

4. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-III is not required for any other group from Groups I-III and Groups I-III have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

5. Irrespective of whichever group applicant may elect, applicant is further required under 35 USC 121 (1) to elect a single disclosed embodiment to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added. Currently, claims 1 and 31 are generic.

I. If Group I is elected, the election of a **specific** glycoprotein composition:

A) Anti-CD20 specific monoclonal antibody
B) Anti-HER2 specific monoclonal antibody
C) Anti-VEGF specific monoclonal antibody
D) Anti-IgE specific monoclonal antibody
E) Tumor necrosis factor-immunoglobulin G1 chimera
F) Antibody-immunoadhesin chimera

II. If Group III is elected, the election of a **specific glycoprotein composition** (see above) used to treat a **specific** disease.

These antibodies and immunoadhesins are patentably distinct because their structures and modes of action are different.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. During a telephone conversation with Jeffrey S. Kubinec on 3/18/99, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-20 and 35-44 and the specific embodiment, anti-CD20 specific monoclonal antibody. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-9, 17-19, and 40 (non-elected claims of Group I) and claims 21-34 (non-elected claims of Groups II and III), are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Claims 1-7, 10-16, 20, 35-39, and 41-44 read on the elected embodiment and are under consideration.

Specification

9. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e). An application in which the benefits of an earlier application are desired must contain a specific reference to the earlier filed application(s) in the first sentence of the specification (37 CFR 1.78). A statement reading "This application claims priority to Provisional Application Serial No. 60/063,871, filed 10/31/97" should be entered following the title of the invention or as the first sentence of the specification.

10. The specification is objected to because it has a large blank space on page 14 and there are no descriptions for the oligosaccharide structures..

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-7, 10-16, 20, 35-39, and 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is indefinite and ambiguous to recite "CH2 domain" in claim 1, line 2. It is suggested that said term be changed to "immunoglobulin CH2 domain".

The recitation "glycoprotein having at least one CH2 domain....substantially free of the glycoprotein having at least one CH2 domain and....its CH2 domain" in claim 1 is very confusing. Further, the recitations in claim 10 and claim 20 contradict the compositions disclosed in the specification in pages 5-6 wherein the composition comprises a glycoprotein having a CH2 domain that has substantially of G2 and G-2 oligosaccharides.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-7, 10-16, 20, 35-39, and 41-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Patel al. (WO9730087) in view of Maloney et al. (#57).

Patel et al. teach a human IgG1 (page 7, second paragraph, in particular) monoclonal antibody (see page 12, paragraph 1, in particular) glycoprotein preparation (see page 1, first paragraph, in particular) in which the composition is substantially free of the CH2 domain (see page 4, paragraph 4 in particular) containing N-linked G0, G2, and G-2 oligosaccharide domains (see page 20 in particular and page 14, paragraphs 3 and 4, in particular). Patel et al. teach that the monoclonal antibody compositions can be used to treat cancer (see page 7, paragraph 3, in

particular). Patel et al. teach that the antibody composition can be a pharmaceutical composition in a pharmaceutically acceptable carrier (page 8, second paragraph, in particular) and can be used in the manufacture of a medicament for the treatment of diseases (see page 7, paragraph 4, in particular). In the manufacturing process, it would be obvious to place on the medicament of manufacture a container label specifying the intended use of the medicament for treatment of cancer. Patel et al. teach that the antibody can be from any species (see page 8, fourth paragraph, in particular), preferably those that can mediate complement lysis (see page 9, first column, in particular) and does not limit what antigen can be targeted by the antibody.

Patel et al. differ from the claimed invention in that they do not teach that the monoclonal antibody of the composition is an anti-CD20 monoclonal antibody.

Maloney et al. teach that anti-CD20 antibodies comprising human IgG1 can be used to lyse cells in vitro via antibody-mediated lysis and can be used to treat cancer in humans (see abstract, in particular). Maloney et al. also teach that anti-CD20 antibodies have been used in pharmaceutical compositions (see page 2458, left column, in particular) to treat patients with lymphomas.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to substitute anti-CD20 antibodies as taught by Maloney et al. into the pharmaceutical composition taught by Patel et al. with a reasonable expectation of success in arriving at the claimed invention because Patel et al. teach the CH2 domain lacking G0, G1, and G2 of a human IgG1 monoclonal antibody preparation which can be used to treat cancer through the lysis of cells (see page 7, paragraph 3, in particular) while Maloney et al. teach that anti-CD20 antibodies comprising human IgG1 can be used in pharmaceutical compositions to lyse cells in vitro via antibody-mediated lysis to treat lymphomas in humans (see abstract, in particular).

15. No claim allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara Custer whose telephone number is (703) 305-1690. The examiner can normally be reached Monday through Friday from 9:00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014 or (703) 308-4242.

Tara Custer
Patent Examiner
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June 15, 1999

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